

#### IN THE

## Supreme Court of the United States

OCTOBER TERM, 1977

No. 77-1503

LUTRELLE F. PARKER, Acting Commissioner of Patents and Trademarks,

Petitioner,

VS.

MALCOLM E. BERGY, et al.,

Respondents.

### BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

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Respondents, Malcolm E. Bergy et al., oppose the petition for writ of certiorari to the United States Court of Customs and Patent Appeals.

#### QUESTION PRESENTED

Petitioner's statement of the question presented for review should be replaced by the statement of the issue made by the Court below. The Court below recognized the issue as

whether the uncontroverted fact that the biologically pure culture, as claimed, is alive removes it from the categories of inventions enumerated in § 101 (emphasis in original) (P. Appendix A 10a).

Most importantly, the question presented is *limited* to *microorganisms* and does *not* extend to other living organisms. This was expressly stated by the Court below (P. Appendix A 11a).

#### STATUTE INVOLVED

The only statute involved in rejecting the claimed subject matter as nonstatutory is 35 U.S.C. § 101 (P. 2).

Reference in the Petition to the Plant Patent Act of 1930 (P. 2-3) is misleading because the application for the invention of the present case was *not* filed in the United States Patent and Trademark Office under said Act.

#### STATEMENT OF THE CASE

This case concerns a biologically pure culture of a novel microorganism ' which was the subject of a patent application filed by the respondents in the United States Patent and Trademark Office on June 10, 1974. The invention is claimed in the patent application by two types of claims. The first type of claim is a process claim using the biologically pure culture of the novel microorganism to make the useful antibiotic lincomycin. The second type of claim is directed to the biologically pure culture of the novel microorganism itself. The Patent Examiner allowed the process claims, but rejected the claim to the biologically pure culture of the novel microorganism under 35 U.S.C. § 101. On appeal, this rejection was affirmed by the United States Patent and Trademark Office Board of Appeals. The decision by the Board of Appeals was reversed by the United States Court of Customs and Patent Appeals in a decision handed down on October 6, 1977. In re Bergy et al., 563 F.2d 1031 (1977).

<sup>1&</sup>quot;P." refers to the Petition for Writ of Certiorari to the United States Court of Customs and Patent Appeals filed in the present case.

<sup>&</sup>lt;sup>2</sup> The biologically pure culture of the novel microorganism is classified as an actinomycete, and *not* as a bacterium. Also, the novel microorganism was discovered in a soil sample ob lined from Arizona. There is no evidence that the novel microorganism could be found in any other Arizona soil sample, or in a soil sample from any other area.

<sup>&</sup>lt;sup>3</sup> Four process claims were allowed. Similar process claims are found in hundreds of U.S. patents relating to the production of antibiotics.

<sup>&</sup>lt;sup>4</sup> Both the allowed claims and the rejected claim recite a living microorganism. This living microorganism is the *same* in both instances, and it is characterized by a single disclosure in the patent application covering twelve (12) pages of the record filed in the United States Court of Customs and Patent Appeals (R. 8-19).

#### ARGUMENT

The United States Court of Customs and Patent Appeals in a decision reported at 563 F.2d 1031 (P. Appendix A 1a-29a), reversed the Board of Appeals and held that the biologically pure culture of the novel microorganism, claimed in respondents' patent application (R. 6-27), is patentable subject matter under 35 U.S.C. § 101. Petitioner, the Acting Commissioner of Patents and Trademarks, seeks review by this Court on a writ of certiorari. 28 U.S.C. § 1256.

The decision by the United States Court of Customs and Patent Appeals is not in conflict with any decision of another court of appeals on the same matter, and is not an exercise of legislative prerogative. Further, the decision does not conflict with any decision by this Court.

The decision by the United States Court of Customs and Patent Appeals is another example of the Court's clear understanding of microbiological inventions and the proper application of the Patent Statute (35 U.S.C. § 101) thereto. The expertise of the United States Court of Customs and Patent Appeals in microbiological patent law, as evidenced by its decisions, benefits both the public and the microbiological inventor. Accordingly, the petition for writ of certiorari should be denied.

The subject matter of this case represents technology which has been on the American scene for a number of years. The production of antibiotics by fermentation procedures has been particularly evident since the 1940's. Thus, this case, though it concerns a novel microorganism and a novel process, is representative of well-known antibiotic technology.

Petitioner erroneously extends the scope of the United States Court of Customs and Patent Appeals decision to "living things." The decision of the Court below is expressly limited to a factual situation wherein a biologically pure culture of a living microorganism is claimed. By extending the Court's decision to "living things" other than microorganisms, the Petitioner enters areas where issues of patentability will have to be decided on a case-by-case basis (P. Appendix A 11a).

Petitioner raises an assortment of emotional points in an effort to sustain his position. For example:

—Since the number of living things is vast, the decision opens an enormous range of subject matter to patentability. (P. 6).

This fear is unfounded because the decision of the Court below does not extend to "living things" in general; it is expressly limited to microorganisms. (P. Appendix A. 11a).

—Moreover, the nature of living things—especially microorganisms—creates a serious risk that a patent monopoly will exceed its lawful limits. (P. 7n. 6).

<sup>5 &</sup>quot;R." refers to the printed record filed in the United States Court of Customs and Patent Appeals. Petitioner has acknowledged that a copy of this record has been lodged with the Clerk of this Court.

<sup>&</sup>lt;sup>6</sup> Other significant decisions by the United States Court of Customs and Patent Appeals in recent years in the microbiological area are In re Arzberger, 112 F.2d 834; In re Argoudelis et al., 434 F.2d 1390; In re Mancy et al., 499 F.2d 1289; and Feldman v. Aunstrup, 517 F.2d 1351, cert. denied, 188 USPQ 720 (1976).

<sup>&</sup>lt;sup>7</sup> The record shows that this claimed entity meets all the statutory requirements for patentability as set out by the patent statute (P. Appendix A 3a).

It is not clear to the respondents how a patent claim to a living microorganism will create "a serious risk that a patent monopoly will exceed its lawful limits." As stated previously, process patent claims using living microorganisms have been in existence for a number of years in hundreds of patents. The respondents are not aware of any special enforcement problems with these claims.

—The difficulty of describing and understanding microorganisms creates problems in determining whether competitive developments are lawful or infringing. (P. 7 - n. 6).

It is well known that a microbiologist is trained in describing and understanding microorganisms. Thus, where difficulties arise concerning these matters, for example, in the enforcement of microbiological patent rights, then obviously the microbiologist will have to be used to help resolve the problem. This has always been the case with microbiological patent enforcement.

—Unless the instant decision is reversed, the policy problems of genetic engineering already highly controversial, will be further complicated by crystallized patent considerations. (P. 7).

It should be recognized that the subject matter of the present ease does not involve genetic engineering

using microorganisms. However, since inventions using genetic engineering of microorganisms are expected to be affected by the decision in the present case, it is appropriate to appreciate the nature of such work. Though the art of genetic engineering using microorganisms is presently of great moment to the scientific community, it is abundantly clear that the imagined horrors initially associated with such work by some members of the public were not well taken. Presently, the scientific community recognizes that this type of work does not pose such threats to society. On the contrary, microbial genetic engineering is being demonstrated as well-controlled work which holds great promise in many areas, e.g. medicine, food, and the environment. It is precisely the type of scientific progress for which the patent system can function as an incentive. The granting of patents for such inventions does not automatically grant the right to practice the inventions where the public health or safety can be affected. Our present system of regulating the production and use of medicines and foods functions apart from the patent system to protect public interests. Surely, there can be no question but that the fruits of microbial genetic engineering also will be under such legislated controls.

The Petitioner refuses to accept 35 U.S.C. § 101 for what it states. Further, the Petitioner refuses to recognize that in the legislative history of the patent statute there is no mention that an invention should be denied patent protection solely because it is living. Rather, the Petitioner resorts to a series of speculations

<sup>\*</sup> The Petitioner's reference to Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347, 1379-1383 (C.A. 5), certiorari denied, 429 U.S. 1094, and Jeffery, The Patentability and Infringement of Sport Varieties: Chaos or Clarity? 59 J. Pat. Off. Soc'y 645, 654-657 (1977) as apparent support for the above points, supra (P. 7) is inappropriate since these references relate to plants and the Plant Patent Act, neither of which is involved in the subject of this case.

See "DNA furor abates," Chemical Week, November 9, 1977, at 21.

concerning the Plant Patent Act <sup>10</sup> and concludes that Congress did not intend that the patent statute be used to protect patentable inventions which happen to be alive. In short, the Petitioner is attempting to write in the word "dead" as a prerequisite for a patentable invention. If the Petitioner desires such a change in the patent statute, then the proper procedure is through Congress. The Court below clearly saw this situation and rightly refused to judicially legislate such a change in the patent statute.

#### CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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<sup>&</sup>lt;sup>10</sup> The legislative history of the Plant Patent Act clearly shows that the purpose of enacting the act was to benefit agriculture. In re Arzberger, 112 F.2d 834. There was no concern expressed about matters living or dead.